4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

RIN 0910-AG94

[Docket No. FDA-2013-N-0500]

Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Correction and Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction and extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is correcting, and extending the comment period for, the proposed rule that appeared in the Federal Register of November 13, 2013. In the proposed rule, FDA requested comments on the proposal to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change. The proposed rule published without a reference or a link to the accompanying Regulatory Impact Analysis. The Agency is taking this action to correct this omission and to extend the comment period in response to requests for an extension to allow interested persons additional time to submit comments on the proposed rule.

DATES: FDA is extending the comment period on the proposed rule published November 13, 2013, at 78 FR 67985, and on information collection issues under the Paperwork Reduction Act of 1995. Submit either electronic or written comments on the proposed rule by March 13, 2014.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 11, 2014 (see the "Paperwork Reduction Act of 1995" section of the proposed rule).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0500 and/or Regulatory Information Number (RIN) 0910-AG94, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of the proposed rule.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-0500 and RIN 0910-AG94 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the

heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janice L. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6304, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 13, 2013 (78 FR 67985), FDA published a proposed rule with a 60-day comment period to request comments on the proposal to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired information in advance of FDA's review of the change. Comments on the proposal to permit holders of abbreviated new drug applications to distribute revised product labeling that differs in certain respects, on a temporary basis, from the labeling of its reference listed drug upon submission of a "changes being effected" supplement will inform FDA's rulemaking.

The proposed rule published without reference or a link to the accompanying Regulatory Impact Analysis. Accordingly, the following corrections are made to FR Doc. 2013-26799, appearing on page 67985, in the Federal Register of November 13, 2013:

1. On page 67996, in the first column, at the end of section IV. Analysis of Impacts, the following is added as a third full paragraph: "The full discussion of economic impacts is available in docket FDA-2013-N-0500 and at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm (Ref. 3)."

2. On page 67997, in the third column, the following is added as a third reference: "3. Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm."

The Agency has received requests for a 60-day extension of the comment period for the proposed rule. These requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 60 days, until March 13, 2014. FDA also is extending the comment period for information collection issues under the Paperwork Reduction Act of 1995 for 60 days, until February 11, 2014. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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